Impact of an educational video as a consent tool on knowledge about cure research among patients and caregivers at HIV clinics in South Africa

Melany Hendricks[1]*, Gonasagrie Nair[1,2], Ciara Staunton[1], Michael Pather[3], Nigel Garrett[2], Dianno Baadjies[1], Martin Kidd[4] and Keymanthri Moodley[1]

[1] Centre for Medical Ethics and Law, Stellenbosch University, South Africa
[2] Centre for the AIDS Programme of Research in South Africa, University of KwaZulu-Natal, Durban, South Africa
[3] Division of Family Medicine and Primary Care and Department of Statistics, Stellenbosch University, South Africa
[4] Department of Statistics, Stellenbosch University, South Africa

Abstract

Background: Despite increasing access to antiretroviral therapy in low- and middle-income countries, only 54% of eligible individuals were receiving treatment in Africa by 2015. Recent developments in HIV cure research have been encouraging. However, the complex science and procedures of cure research render the informed consent process challenging.

Objective: This study evaluates the impact of a video tool on educating participants about HIV cure.

Methods: A questionnaire assessing the content of the video was administered to adults recruited from two clinics in South Africa. Patients and their care partners, who provided voluntary informed consent, were included in the study. The questionnaire was administered in each participant's home language before, immediately after and at 3 months after viewing the video, in an uncontrolled quasi-experimental 'one group pre-test–post-test' design. Scoring was carried out according to a predetermined scoring grid, with a maximum score of 22.

Results: A total of 88 participants, median age 32.0 years and 86% female, were enrolled and completed the pre- and post-video questionnaires. Twenty-nine (33%) completed the follow-up questionnaire 3 months later to assess retention of knowledge. Sixty-three (72%) participants had a known HIV-positive status. A significant increase (10.1 *vs* 15.1, P=0.001) in knowledge about HIV and HIV cure immediately after viewing the video was noted. No statistically significant difference in knowledge between HIV-positive and -negative patients was noted at baseline. After 3 months, a decrease in performance participation (14 *vs* 13.5, P=0.19) was noted. However, knowledge scores achieved after 3 months remained significantly higher than scores at baseline (13.5 *vs* 9.5, P<0.01).

Conclusions: This research showed that a video intervention improved participants' knowledge related to HIV, HIV cure research and ethics, and the improvement was sustained over 3 months. Video intervention may be a useful tool to add to the consent process when dealing with complex medical research questions.

Keywords: HIV cure research, video, informed consent

Introduction

Access to antiretroviral therapy (ART) remains sub-optimal in low- and middle-income countries (LMICs) [1,2]. Increasing access to ART will decrease transmission provided that viral suppression is achieved by individuals on treatment. Viral suppression in turn is dependent on a number of social, behavioural and biomedical factors, including remaining engaged in care [1] and adherence to ART. The high HIV burden in sub-Saharan Africa (SSA) [2], coupled with high proportions (up to 75%) of individuals with HIV who remain unsuppressed [3], make it unlikely that treatment alone will adequately control the infection in this region. Furthermore, logistical and financial challenges associated with lifelong provision of ART compound the challenge to control the HIV pandemic.

Reports of undetectable viral loads sustained for a longer period than predicted amongst adults (the Visconti cohort) [4], an infant (the Mississippi baby) [5] and, in South Africa, a 9-year-old child [6], confirmed the plausibility of a functional cure for HIV. 'Functional cure' is the term used to indicate the long-term control of HIV replication without treatment. A functional cure differs from an 'absolute or sterilising cure' in that the latter is characterised by the total eradication of replication-competent proviruses from the body [7]. In all three cases, very early initiation of ART in acute HIV infection was important. These developments stimulated HIV cure research and fast-tracked the exploration of the ethical implications of cure research.

HIV pathogenesis and HIV cure strategies remain poorly understood [8], particularly in communities most affected by HIV, posing major challenges for cure research. Poor understanding of cure concepts may raise false hopes of an absolute cure amongst research participants [9]. This may result in 'curative misconception' influencing the decision to participate in a 'cure' research study, lowering the appreciation of the associated risks, increasing risky behaviour and refusal to adopt proven treatment strategies [8]. The risk of HIV infection worsening, and the development of resistance when treatment is discontinued, must be appreciated by potential participants in HIV cure trials aimed at eradication of viral reservoirs. It is thus essential that messages conveyed to communities and these potential participants are clear and consistent to avoid misconceptions.

Given the potential risks that are integral to HIV cure research, and the importance of respecting participant autonomy, informed consent [9] cannot be over emphasised. The informed consent process extends beyond the legal duty of the researcher to disclose information and to ensure participant understanding of the disclosed information [10]. Research has exposed the gaps in the informed consent process, revealing that participants failed to understand key research concepts [11]. South African literature [12] concurs that the current consent process may not guarantee sufficient understanding of the requirements for and the implications of trial participation. Therefore, participants may lack

*Corresponding author: Melany L Hendricks, Centre for Medical Ethics and Law (CMEL) Department of Medicine, Faculty of Medicine and Health Sciences, Stellenbosch University, South Africa
Email: mlh@sun.ac.za

understanding to make an informed decision regarding enrolment and ongoing participation in a clinical trial [12,13]. Language barriers and lack of understanding impact on effective communication of research-related information, especially with respect to culturally sensitive issues such as blood collection in sub-Saharan African countries [14]. Retention of knowledge is an additional issue that needs to be considered [15].

Notwithstanding reported benefits, the use of video in medical research is suboptimal [16] and its effectiveness in improving understanding of consent information in clinical trials is unclear [17,18]. A Cochrane review [17] concluded that the heterogeneity of results is secondary to differences in study design, population and measurement of the effectiveness of the intervention. However, technological advances and new approaches to research may lead to increased use of video recordings, especially in the primary health care environment [19]. The use of video recordings may be useful in qualitative research [16]. In quantitative studies, video has been used specifically for health education [20,21]. In a randomised, controlled trial aimed at assessing the impact of video on improving the consent process, participants reported that the video improved understanding of concepts related to clinical trials and increased acceptability of the patients' participation by family members [22].

In order to explore the impact of audio-visual material on the understanding of consent information, our study team developed a 15-minute video on HIV cure, treatment and prevention to raise awareness about HIV cure research. The aim of this research was to evaluate the effectiveness of the educational video as a tool to promote understanding of HIV cure research among patients and caregivers in South Africa. The objectives were to determine retention of knowledge over a 3-month period, to evaluate whether understanding differs with HIV status, and to ascertain preference for knowledge dissemination methods.

Methods

The narrative of the video revolved around two HIV-infected women who establish a supportive friendship after meeting in an HIV clinic. Their conversation includes discussions of HIV prevention strategies, the importance of adherence to ARVs, proven strategies to prevent and treat HIV infection and, as the story unfolds, early HIV cure 'successes', the benefits and risks of HIV cure research, the role of the research ethics committee and the Medicines Control Council of South Africa. Information was presented in English with subtitles in Afrikaans, isiXhosa and isiZulu. The study forms part of a larger study on the ethical implications of HIV cure research, involving three sites (University of North Carolina, Stellenbosch University, Guangzhou University).

The effectiveness of this educational video was evaluated through an uncontrolled quasi-experimental study, namely the 'one group pre-test–post-test design'. The pre-test measurement served as a control 'group'. Knowledge was measured at three time-points: before the video was shown; within 15 minutes after participants had viewed the video (to ensure that no other outside factors could influence the answers); and 3 months after the initial viewing. Knowledge is understood as conceptual knowledge [23], referring to inactive knowledge about facts, concepts and principles used in problem-solving. While knowledge requires some level of understanding, the quality of understanding with conceptual knowledge is superficial, meaning that knowledge is stored in memory as a copy of the original information.

The questionnaire used to measure the participants' knowledge was based on the contents of the video. One mark was given for every correct answer. All questions had one correct answer except for question 7 which had two correct answers. Questions 18–20 were not scored. The correct answers summed to obtain a complete score of maximum 22 points. Any differences in knowledge were assumed to be due to the video intervention [24].

Recruitment

Doctors, nurses and counsellors at the study sites informed potential volunteers about the study and ascertained their willingness to participate. Only adult volunteers receiving treatment at CAPRISA (Centre for the AIDS Programme of Research in South Africa) and FAMCRU (Family Clinical Research Unit) and their adult family members or carers were included in the study. Volunteers, family members and carers willing to participate were given relevant information prior to consenting. Participants reported on their HIV status. HIV-positive patients and their HIV-negative family members or care partners were included as they are all affected by HIV and future cure research.

Data Collection

The study questionnaire was initially piloted on five patients per language group. All participants were provided with study information, including potential risks and/or benefits of participating. Informed consent was obtained. Trained research assistants administered a questionnaire to assess knowledge and understanding related to HIV cure research based on the content of the video. A questionnaire covering the topics outlined in Table 1 was administered.

Fifteen minutes after viewing the video, the participants were requested to complete the same questionnaire. Participant score before and after watching the video was recorded and statistically analysed. Questionnaires were administered in the preferred language of the participant, and took approximately 15 minutes to complete.

Given that there is some doubt [13] about efficacy of learning concepts after a single viewing of an educational video over the long term, the questionnaire was administered again after 3 months to assess retention of knowledge.

Statistical analysis

Testing for possible significant change in average knowledge scores between the pre- and post-testing periods was conducted using mixed-model repeated measures analysis of variance (ANOVA). This took into account any possible loss to follow-up.

Ethical considerations

The video considered the broader socio-political issues related to HIV in South Africa. Information given in the video had to be factually correct, and was delivered in a manner that would not cause further stigmatisation of HIV or AIDS and the marginalisation of persons living with the disease. This video does not promote the involvement of participants in future HIV cure studies. Rather, its purpose is to educate and empower participants about HIV cure research in general. Messages about treatment and prevention were deliberately reinforced to ensure that cure research was not promoted as a substitute for treatment and prevention.

Due consideration was given to the privacy, confidentiality and anonymity of participants. All questionnaires are stored in a secure, locked space. Names did not appear on the questionnaire. A unique code was given to each participant and the information linking the name to the code is stored on a password protected database.

This study was approved by the Health Research Ethics Committee (HREC N15/01/005) at Stellenbosch University (SU) and was conducted in accordance with the ethical guidelines and principles of the international Declaration of Helsinki 2013 and the South African Guidelines for Good Clinical Practice 2006. The University

of KwaZulu-Natal Behavioural Research Ethics Committee endorsed the approval of the SU HREC. Permission to conduct the research was obtained from the relevant hospital and institutional authorities in the two provinces.

Results

A total of 88 adults from the FAMCRU clinic in the Western Cape (WC) and the CAPRISA Ethekwini Clinical Research Clinic in Durban, Kwa Zulu Natal (KZN) participated in the study. Forty-eight (55%) adults were recruited from the WC and 73 (86%) were women. Sixty-one participants (69%) completed grade 11 to 12 as their highest level of education, 22 (25%) completed grade 7 to 10, one participant (1%) had completed grade 3, and 5 (6%) had at least one year of tertiary studies. Seventy-two percent of participants were HIV positive (HIV+), 20% were HIV negative (HIV-) and 5% chose not to disclose their status. Only 3% of the sample did not know their HIV status. Thirty-four (40%) participants identified themselves as isiXhosa, 10 (12%) identified as coloured or mixed race, 35 (40%) identified as African and the rest identified as either mixed race, Zimbabwean or Sotho. The median age of participants was 32 years (25th percentile: 29 years; 75th percentile 39 years). After 3 months, the questionnaire was administered to 29 participants in the WC who were available at the time of the follow-up. The rest of the WC and the KZN group was lost to follow-up.

Table 1. Topics covered in the questionnaire

Questions	No.	Content
Demographic information		Age, gender, highest level of education (HLOE), language, HIV status; ability to read
HIV treatment	1	When to take meds
	2	Use of pill box
	6	ARV and traditional medicine
	7	What to do when taking ARV and traditional medicine
	8	Can ARVs be taken with traditional medicine?
HIV prevention	3	How to protect self from getting HIV
	4	What to do in case of unprotected sex
	5	Testing when sexually active
HIV cure	9	What are researchers looking for now in terms of HIV?
	10	Mississippi baby
	11	Impact of cure researchers on HIV treatment
	12	Berlin patient
	12.1	Did this treatment work on others?
	12.2	Explain answer
	13	Remission
	14	Risks of participating in HIV cure research
	17	Is there a cure for HIV?
	17.1	Explain
Research	15	Health Research Ethics Committee (HREC)
	15.1	Function of HREC
	16	Medicines Control Council (MCC)
Video	18	Learning self-rated score
	19	Opinion about video
Preferred medium for receiving Information	20	Social media; verbal; written; television; or all

As is shown in Figure 1, there was a significant improvement ($P \leq 0.01$) in scores related to knowledge after participants had watched the video. The KZN sample had a higher level of education than the WC sample. Although the KZN mean (10.5) was higher than the WC mean (9.5) at baseline, this difference was not statistically significant ($P=0.06$). In the test after watching the video, the KZN mean (16) was significantly higher ($P=0.01$). There was no difference in knowledge between HIV+ and HIV- subjects at baseline, and there was a trend that the HIV+ subjects increased their knowledge more than HIV- ($P=0.10$) from before to after, although this difference was not statistically significant. Previously learned knowledge remained intact. After 3 months, 29 of the 49 WC participants were tested again to determine knowledge retention. Knowledge retention decreased, though this decrease was not statistically significant ($P=0.20$). However, knowledge retained about the content of the video remained statistically significantly higher than at baseline (9.5 *vs* 13.5, $P \leq 0.01$) (Figure 1).

The video intervention improved conceptual knowledge on the role of the research ethics

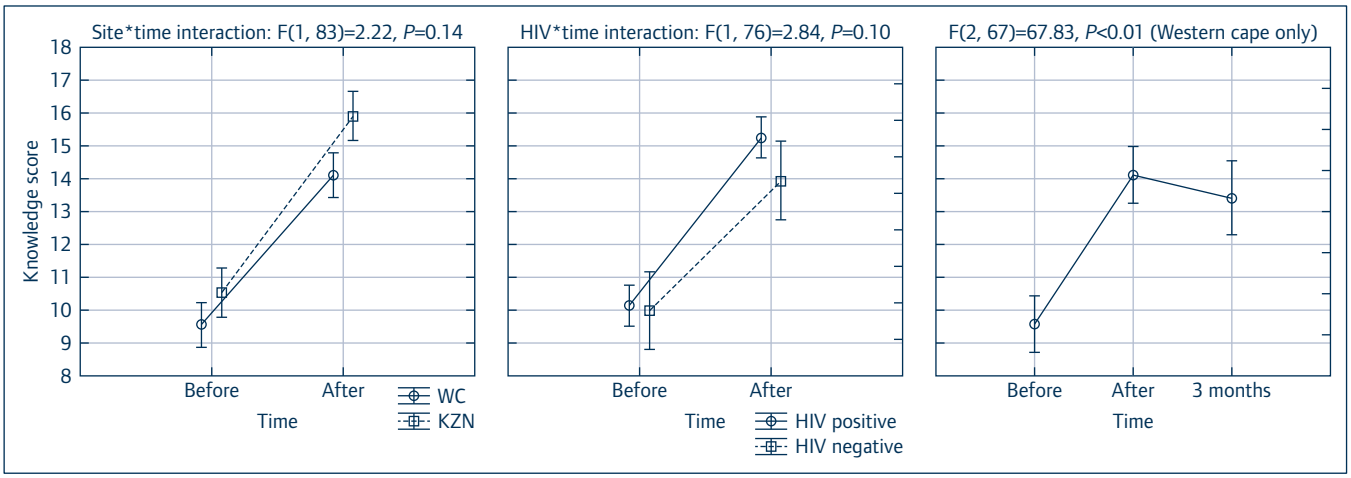

Figure 1. Knowledge scores before and after the video. Vertical bars denote 0.95 confidence intervals

committee and the role of the Medicines Control Council in a clinical trial, but had less impact on knowledge acquired during regular clinic and research visits. Participants did not change their views on the concomitant use of ARVs and traditional medicine, and continued to acknowledge that their simultaneous use was possible despite the new information that it should be discussed with their doctors prior to use. Some improvement was noted in the understanding of concepts such as 'remission' and risks associated with HIC cure research, but the improvement was not statistically significant.

Thirty-two (36%) participants preferred to receive information in all the available mediums. Twenty-one (23%) participants preferred to receive information about research verbally, and 18 (21%) preferred to obtain information visually. Only 6% of the participants gave social media as the mode of choice for receiving information.

Discussion

This study results indicate that, overall, audio-visual technologies may improve understanding and may be used to complement text and verbal information during the consent process for clinical research. Knowledge about HIV and HIV cure improved after participants had watched the video. Participants with a higher level of education (KZN sample) and those who were HIV+ derived more benefit from their exposure to the video intervention. Previously learned knowledge remained intact. After 3 months, knowledge retention decreased, although this decrease was not statistically significant. However, knowledge retained about the content of the video remained significantly higher than at baseline.

The fact that new concepts (remission) remained poorly understood, and information learned prior to the intervention were maintained despite the intervention, suggests that the complementary use of video with discussion is indicated so that unclear information or information conflicting with prior learned knowledge may be clarified [25]. The combination of video and discussion may enhance the quality of HIV knowledge, knowledge about HIV cure and research knowledge so that a deeper level of understanding can be achieved [10,26,27].

This study concurs with South African studies [18,27] that found that video is an acceptable, cost-effective educational tool in developing countries. This finding corresponds with other international studies [19,28], which found that multi-media tools that deliver information in a clear, consistent and unbiased manner [17] are easy to use [29,30] and can be as effective as face-to-face interaction [28]. Video, in particular, frees staff to attend to other duties while patients control the pace at which information is viewed [17].

Our results concur with other studies that the value of audio-visual tools increases with increasing level of education [9,10,15,28]. The higher the level of literacy of the target population, the more effective the strategies developed to enhance understanding of information shared during the informed consent process [28]. Compared to the WC participants, the KZN cohort had a higher level of education and scored higher when compared to the WC sample. It must, however, be noted that the CAPRISA participants have been involved in HIV research for many years, which may have influenced the results discussed above. Other studies [28,29] report that the use of video in the participants' first language is considered a cost-effective way of delivering uniform information to those who have low levels of literacy and those whose visual impairment renders them unable to read printed material. This study agrees with the literature [32] which concludes that further studies are warranted to determine how the characteristics of an educational video may be altered to increase its efficacy for use amongst illiterate individuals and those with lower levels of education.

The findings of this study align well with other literature [27] regarding long-term knowledge retention. It found some loss of knowledge after 3 months, while knowledge remained higher than at baseline. As the sample size was small, it is recommended that this be tested with a larger group.

Only 6% of participants in this survey preferred social media as the mode of choice for the receipt of research-related information. This could be because cellular data in South Africa is still expensive, and in some cases internet technologies might not always be accessible or reliable. In addition, some older persons may not be as comfortable with technology and therefore prefer to receive information in formats other than social media.

The quasi-experimental design was chosen because of the small sample size and the requirement to implement the intervention quickly. This study design has been criticised [30] but has still been used successfully in LMICs [31] and was also employed to test understanding before and after the showing of an educational video [25]. In this pre-test – post-test design, the pre-test served as the control group. The minimal time delay before and after the intervention decreased the impact of potential confounding factors so that improvement noted is most likely a result of the intervention, thereby mitigating the weaknesses resulting from the lack of randomisation. The absence of the KZN participants at the 3-month assessment also impacted on the results after viewing of the video.

We postulate that video could be used in waiting room education sessions as part of the ongoing informed consent process for research and for clinical use. However, it is important to note that 'incidental viewing' is not as effective as viewing occurring in a structured setting where full attention is directed toward the video [33]. Additional research is required in this area.

Language has been identified as a barrier amongst adults with low literacy levels [14]. The language used in this video was the second language of most participants, which may have negatively impacted understanding. The audio of the video was not translated into the languages prevalent in the two provinces because of cost constraints, and instead subtitles in the local languages were used. It is therefore recommended that the video should be presented in the preferred language. The full advantages of an audio-visual presentation may have been diminished because participants had to concurrently read the subtitles. Although most participants in this study indicated that they could read in English and in their home language, no test was implemented to test reading ability.

The success of strategies to improve understanding of concepts related to informed consent is dependent on factors that include level of literacy [15]. It may therefore be worth conducting a randomised comparison of the use of subtitles in a video of a secondary language before any real conclusions can be drawn.

The issue of unaffordable costs, especially in LMICs, with respect to video production may be addressed by the in-house production of audio-visual material and the development of videos that address common themes in the informed consent process, which can be supplemented with study specific audio-visual or written material. Further research is required to gauge the effectiveness of 'incidental' as opposed to structured viewing in relation to knowledge acquired. Research to ascertain the impact of subtitles on conceptual knowledge may improve the effectiveness of using this medium in participant education.

Conclusion

This research showed that a video intervention improved participants' knowledge of HIV, HIV cure research and ethics, and was sustained over 3 months. Video interventions may be a useful tool to add to the consent process when dealing with complex medical research questions.

Acknowledgements

The authors would like to acknowledge Tygerberg Hospital, in particular the FAMCRU Clinic; CAPRISA and Zulpha Geyer for editorial support. The authors thank all the study participants.

Authors' contributions

MH was involved in designing the methodology, conducted interviews, analysed data, drafted the article and revised all subsequent versions.

GN conducted interviews, assisted with drafting of the article and commented on subsequent drafts.

CS was involved designing the methodology, conducted interviews, analysed data and commented on all versions on the article.

MP was involved in data analysis and commented on all drafts of the article.

NG commented on the article.

DB was involved in data collection.

MK was responsible for statistical analysis and commented on all drafts of the article.

KM is the Principal Investigator of the project. She was involved in designing the methodology and data analysis. She commented on all drafts of this article.

Funding

Support for this work was provided by the Brocher Foundation, the UNC Centre for AIDS Research [NIAIAD P30-AI50410], and the Social and Ethical Aspects of Research on Curing HIV (searcHIV) Working Group [NIAID R01A108366-01]. The Working Group's composition and rationale is explained at http://searchiv.web.unc.edu/.

Competing interests

The authors declare that they have no competing interests.

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